REMARKS/ARGUMENTS

I. Status of the Claims

Claims 1-15 are currently pending, with claims 1-7 and 11-15 withdrawn from consideration as directed to a non-elected invention. Upon entry of this amendment, claims 8-10 are amended and claims 1-7 and 14-15 canceled without prejudice or disclaimer. The canceled claims are canceled solely because they are directed to non-elected subject matter. Applicants reserve the right to reintroduce the unamended or canceled claims in this or another application. Claims 8-13 are thus pending following entry of this amendment.

The amended claims are supported throughout the specification, including, for example, at page 19, line 29 to page 20, line 14.

II. Objections to the Claims

Claims 8-10 have been amended so they no longer recite to non-elected subject matter (i.e., SEQ ID NO:4) as requested.

The abbreviation for human smooth muscle myosin heavy chain has been recited in full as requested.

III. Claim Rejections under 35 U.S.C. §112, First Paragraph

A. Written Description

Under the Written Description Guidelines, a claim directed to a genus (e.g., independent claim 8) can satisfy the written description requirement by, for example, disclosing "relevant identifying characteristics" (Fed. Reg., vol. 66, page 106 (January 5, 2001)). Examples of such characteristics are said to include: (1) structures or other chemical or physical properties, (2) functional characteristics coupled with a known or disclosed correlation between structure and function, or (3) combinations of such identifying characteristics.

The specification and claims satisfy the written description requirement by disclosing several relevant identifying characteristics. For example, the presently pending claims define the claimed polypeptides as comprising an amino acid sequence that has greater than 95%

sequence identity to SEQ ID NO:2 or as comprising SEQ ID NO: 6, 8, 10, 12 or 14, thus satisfying the structural criterion set forth in (1). The claims and specification further satisfy the criterion of (2) by defining the currently claimed proteins as having ATPase or actin binding activity (functional characteristics), and noting that proteins having such activity can include those having greater than 70% sequence identity to SEQ ID NO:2 (see, e.g., page 20, line 8 to page 21, line 13). Claim 8 currently recites that polypeptides with these activities have at least 95% sequence identity. Thus, the specification and claims clearly satisfy the written description requirements as set forth in the Written Description Guidelines.

Furthermore, the current claims are consistent with the conclusion reached in Example 14 of the "Synopsis of Application of Written Description Guidelines" (Synopsis)," which provides examples of the type of analysis used by the Office in evaluating compliance with the written description requirement. Example 14 is directly analogous to the current claims. The claim in Example 14 reads as follows:

A protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A to B.

Because the claim defines the genus in functional terms that are related to a disclosed correlation between structure and function (see Written Description Guideline criterion (2) above), the Synopsis concludes that the disclosure meets the written description requirements with respect to this exemplary claim. Current independent claim 8 is analogous to this claim (i.e., it too links functional characteristics to structural characteristics) and, as noted above, this relationship is fully supported by the specification. So by analogy, claim 8 also satisfies the written description requirements.

B. Enablement

Claims 8 and 9 are also rejected because the specification allegedly does not provide sufficient guidance for one of ordinary skill in the art to make and use the claimed polypeptides without undue experimentation. The Office Action sets forth a number of reasons

to support this contention, but these can be summarized as follows: 1) the claims are overly broad and encompass polypeptides with the defined sequence identity regardless of activity; and 2) the specification does not provide sufficient guidance on how to make or use all polypeptides encompassed within the claims that have any (or no) activity.

In response, it is first noted with respect to the first concern that base claim 8 has been amended to focus on polypeptides with defined sequences and functional characteristics, namely polypeptides:

(a) that comprise an amino acid sequence that has greater than 95% amino acid sequence identity to SEQ ID NO:2, or that comprise the amino acid sequence of SEQ ID NO:6; SEQ ID NO:8; SEQ ID NO:10; SEQ ID NO:12; or SEQ ID NO:14; and

(b) that have ATPase activity or actin binding activity.

Because claim 8 as currently written defines the claimed polypeptides both according to sequence and function, it is submitted that claim 8 as currently worded addresses the first general concern expressed in the Office Action.

The second concern articulated in the Office Action appears to stem from a concern that one of ordinary skill could not identify polypeptides that had the desired activity without undue experimentation. The test for evaluating whether undue experimentation is required to practice the claimed invention was set forth by the Federal Circuit in *In re Wands*, 8 USPQ2d 1400, 858 F.2d 731, 737 (Fed. Cir. 1988):

> [E]xperimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art...*The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine,* or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. (emphasis added).

In view of this guidance, experimentation in this particular instance is not undue if one of ordinary skill in the art can identify polypeptides having the desired activity using methods that are *routine* in the art. It is submitted that this is in fact the case with respect to the current claims.

With respect to polypeptides that comprise an amino acid sequence that has 95% sequence identity with SEQ ID NO:2, the well-known 1989 Creighton reference on proteins teaches that "[p]resent day site directed mutagenesis of a gene allows any amino acids in a protein sequence to be changed to any other, as well as introducing deletions and insertions" ("Protein Structure: A Practical Approach" (Creighton, T.E., Ed.) IRL Press, 1989, pp. 184-185; copy enclosed). The Office Action also acknowledges that "generating variants and homologues of a given polypeptide are known" (Office Action at page 8, first sentence of first complete paragraph). So it is clear that methods of making the claimed variants was routine in the art at least back to the 1989 publication date of the Creighton reference, a date well before the filing date of this application.

Whether a polypeptide had the desired ATPase or actin binding activity could also be determined using routine methods. Methods for determining whether a given polypeptide had these activities could be determined, for example, using assays such as those described and listed on page 43, as well as other assays known in the art.

So one of ordinary skill in the art could both make polypeptides having the sequence characteristics as defined in the current claims and screen these polypeptides for the desired ATPase or actin binding activity using *routine* methods based upon the disclosures in the specification and the general knowledge in the art. In view of the test established by the Federal Circuit, this is all that the law requires. Accordingly, it is submitted that the current claims are fully enabled and that this ground of rejection should be withdrawn.

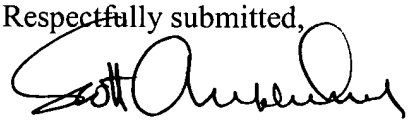
IV. Claim Rejections under 35 U.S.C. §102

Claims 8 and 9 are said to be anticipated under 35 U.S.C. 102 by three polypeptide sequences that have been deposited in public databases.

In response, Applicants reiterate that the currently claimed polypeptide comprise an amino acid sequence that has greater than 95% amino acid sequence identity to SEQ ID NO:2, or comprise the amino acid sequence of SEQ ID NO:6; SEQ ID NO:8; SEQ ID NO:10; SEQ ID NO:12; or SEQ ID NO:14. It is submitted that none of the cited references disclose or suggest polypeptides that satisfy these sequence requirements. Accordingly, it is submitted that this ground of rejection should also be withdrawn.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,



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